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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/449,851 11/24/99 HOLT

K CIMA3.0-035

EXAMINER

000530 HM22/0302
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PHILLIAM, A

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

03/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/449,851

Applicant(s)

HOLT ET AL.

Examiner

Amy E Pulliam

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-18 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the Request for Extension of Time and the Amendment A, both received January 23, 2001, as well as the change of address and Power of Attorney, both received February 6, 2001.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 14, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,516,524 to Kais *et al.* (hereinafter Kais). Kais teaches a pharmaceutical composition comprising doctyl sulfosuccinate (abstract). Specifically, Kais is relied upon for the teaching that double coatings are used for taste masking. Specifically, in column 11, example 6, Kais states that the objective is to eliminate the bitter taste of the drug by applying a double coating. In column 5, lines 55-60, Kais discloses that the composition can be coated with a single coating or multiple coatings, although double coating is preferred. Further, Kais teaches that the second coating can be chosen from pH sensitive polymers. Additionally, Kais states that it is preferable for the first and second coatings to be different, although the coatings can be from the same broad group of compositions, for instance both can be pH sensitive polymers.

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Kais further teaches Eudragit E as an example of a pH sensitive polymer which can be used in the second coating of this invention (c 5, l 60 and c 6, l 48). Applicant does not claim any specific coatings, however, in the examples applicant uses Eudragit E as the taste masking layer. Therefore, Kais's disclosure of Eudragit E reads on applicant's claims to insolubility in saliva at neutral pH and solubility in saliva at acidic pH's as well as solubility in the stomach. Kais's coating must have these same characteristics, as these traits are inherent to the material. Kais further teaches that the coating materials can be between 1 and 50 weight percent of the composition (c 8, l 10-13).

Applicant's arguments filed January 23, 2001 have been fully considered but are not found persuasive. Applicant argues that they require the use of a pH sensitive polymer as the outer taste masking layer. Applicant agrees with the examiner's position that Kais teaches a double layer taste masking coating system and the use of a pH sensitive polymer. However, Applicant states that Kais only exemplifies the use of a pH layer in example VII, where it is shown as the inner layer, rather than the outer layer. The examiner disagrees with this argument. As stated in the original rejection, Kais clearly teaches in column 5, lines 56-63, that a double coating is preferred, and the second coating can be chosen from pH sensitive polymers. Kais does teach that the coatings are both chosen from the same materials, and that the second material is preferably different from the first material. This disclosure does allow that the inner layer could also be a pH sensitive polymer, but it also allows that the outer, taste

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masking layer can be a pH sensitive polymer. Kais does not have to give a specific example to support this disclosure.

Applicant also argues that in column 5, lines 44-49, Kais teaches the pH sensitive polymers would preferably dissolve in the small intestines, and this specifically teaches away from applicant's claimed invention. However, as stated in the original rejection, Kais teaches Eudragit E as an example of a pH sensitive polymer, and applicant uses this same pH sensitive polymer as the taste masking layer of their invention. It is the position of the examiner that solubility characteristics are inherent to the specific coating, and as applicant and Kais use the same polymer for the coating, it must also be soluble in the same environments. Kais does give an example with Eudragit as the inner coating, but this not eliminate the above mentioned teachings with clearly allow for pH sensitive coatings to be the outer layer, and the additional teaching that Eudragit E is an acceptable pH sensitive coating. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kais as applied to claims 1, 4, 5, 14, and 21. Kais teaches applicant's double coating for the purpose of taste masking. Kais does not teach the specific weight percents or

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thicknesses of the coatings. However, it is the position of the examiner that these are limitations that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results. The results must be those that accrue from the specific limitations. Absent any evidence to the contrary, it is therefore the position of the examiner that the weight percents and thicknesses claimed by applicant do not change the function of the dual coating, and therefore do not merit patentable weight. One of ordinary skill in the art would have been motivated to make a dual coated particle with applicant's limitations, based on the teachings of Kais. One of ordinary skill in the art would expect a taste masked formulation regardless of specific percents and thicknesses. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been discussed above. This rejection is maintained for the reasons detailed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E. Pulliam
Patent Examiner
Art Unit 1615
February 28, 2001


THURMAN K. PAGE
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